https://www.federalregister.gov/documents/2002/02/22/R2-59/guidelines-for-ensuring-and-maximizing-the-quality-objectivity-utility-and-integrity-of-information.

As discussed above in the Section on footnote 6, EPA's attempt to align its proposal with OMB's guidelines is misguided.

Footnote 16: See examples from the U.S. Department of Health and Human Services, National Institute of Standards and Technology, U.S. Department of Education, and the U.S. Census Bureau.

In the original Proposal EPA provided no specific "examples" and this vague cite provided very little direction about what EPA was referencing here—making it impossible to review these examples or respond to them.

Footnote 17: https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.

EPA states that other agencies have tools to de-identify information private information, but fails to recognize that these methods are not transferable to EPA's context.[797] EPA links to guidance on de-identification requirements under HIPAA. This guidance provides two methods for de-identifying data: (1) expert determination method, where an expert determines that, after application of statistical and scientific principals and methods, the risk is very small that the information alone or with other available information could be used to identify the subject; and (2) the safe harbor method, requiring that a number of identifiers are removed. The first method requires case-by-case work and EPA has provided no information regarding how EPA could implement it or how much it might cost and thus the feasibility of requiring researchers or EPA to de-identify data this way is questionable. The second method requires removal of much information useful for research that may be necessary to be able to independently validate the research, so it is unclear that it would satisfy the Proposal's demands. Furthermore, the safe harbor method has been shown to provide potentially insufficient privacy protections.[798]

Footnote 18: https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities.

In this footnote, EPA cites to a report by the National Academies for the proposition that "The National Academies have noted that simple data masking, coding, and de-identification techniques have been developed over the last half century. . . " [799] This incorrectly makes it seem as though the National Academies have identified simple techniques to de-identify data for public release without compromising personal piracy. A full review of the report reveals the

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[797] 83 Fed. Reg. at 18,771.

[798] Latanya Sweeney, Ji Su Yon, Laura Perovich, Katherine E Boronow, Phil Brown, and Julia Green Brody, *Re-identifcation Risks in HIPAA Safe Harbor Data: A Study of Data From One Environmental Health Study*, Technology Science (August 28, 2017).

[799] 83 Fed. Reg. at 18,771; National Research Council, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, National Academies Press (2005).

opposite is true, that The National Academies in fact recognize that complex, evolving, and yet undeveloped techniques are needed to resolve these concerns. It offers recommendations that are intended to *improve upon* existing techniques, indicating that this area is under constant change and many advances are left to be made.[800] Further, the report notes this improvement requires "strong partnership between the research community and statistical and research agencies in the design of innovative research on disclosure avoidance techniques and data access modalities and in the implementation of the advances that result from such research."[801] The Proposal takes no steps towards advancing design of new techniques or providing resources to undertake all that needs to be done to make the Proposal remotely feasible.

Further, the Report notes that a changing landscape is making it increasingly difficult to apply past techniques to sufficiently protect data from identification, saying: "Initially, relatively simple data masking techniques, such as top coding income amounts. . . were used to generate restricted data products [,] [d]uring the last decade the increasing risks of confidentiality breaches have led researchers to develop increasingly sophisticated methodologies for restricted data products."[802] They state, "more research is clearly needed to assess the relative ability of different masking methods, and of synthetic data, to reduce the risk of disclosure while preserving data utility."[803] EPA does not acknowledge these newly emerging concerns.

The National Academies recognize the current limitations of producing restricted data that sufficiently limits identifiability to allow it to be made publicly available in a useful form. They note that "well-informed policy making" requires "[r]esearch using detailed confidential data" that cannot be made public—which the Proposal fails to acknowledge to the detriment of the quality of EPA's policy decisions.[804] Just because certain information cannot be made public for legitimate reasons does not mean the government should refuse to use it to inform policy. And much of the data useful for environmental and health research is particularly sensitive—the report notes there is increased vulnerability in "[d]ata with geographic detail, such as census block data" and longitudinal data obtained in panel surveys, which is often salient in environmental research.[805] In the meantime, the National Academies state that more work is needed to allow "[h]igh-quality public-use files" that still assure "the inferential validity of the data while safeguarding their confidentiality."[806]

They also point to broader implications of not implementing sufficient privacy protections that EPA does not consider at all may result from the Proposal. The quality of data collected is likely to suffer as "[i]t is essential that respondents believe they can provide accurate, complete information without any fear that the information will be disclosed inappropriately."[807] Essentially, the report leaves as an open question "decisions about how much disclosure risk is acceptable in order to achieve the benefits of greater access to research data involve weighing the

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[800] *Id.* at 35.
[801] *Id.* at 35.
[802] *Id.* at 27
[803] *Id.* at 28.
[804] *Id.* at 2.
[805] *Id.* at 22.
[806] *Id.* at 2.
[807] *Id.* at 51.

potential harm posed by disclosure against the benefits potentially foregone."[808] Thus, EPA wrongfully points to this report as supporting the notion that simple techniques exist to address privacy concerns. The report recommends only more research to reduce risks and increase data utility along with consultation with data users and providers about these issues—which the Proposal does not implement and thus the report does not support the Proposal.[809]

Footnote 19: https://www.cep.gov/content/dam/cep/report/cep-final-report.pdf; https://www.nap.edu/catalog/24652/innovations-in-federal-statistics-combining-data-sources-while-protecting-privacy; https://www.nap.edu/catalog/24893/federal-statistics-multiple-data-sources-and-privacy-protection-next-steps.

EPA claims that "the National Academies and the Bipartisan Commission on Evidence Based Policy have discussed the challenges and opportunities for facilitating to secure access to confidential data for non-government analysts."[810] The proposal does not explain how these examples are relevant, as there is no indication that secure access to underlying data would meet the requirements of making underlying data "publicly available." Further, even if it were relevant, a review of the sources cited reveal that they do discuss many challenges in this space—which the Proposal does not at all address—and provide no support for the Proposal.

I. Commission on Evidence-Based Policymaking, The Promise of Evidence-Based Policymaking (2017)

This report centers on how to enhance infrastructure to increase the access and use of data between federal agencies to support government policy-making, rather than increase public access to data to non-governmental analysts for purposes of independently validating regulatory science.[811] Further, its focus is to help efforts to make *more* data available for government purposes to better inform policies. The Proposal on the other hand seeks to make data available to validate individual studies while ultimately making *less* data available for EPA to consider as it creates policies.

To the extent the report does speak to making more data *publicly* available, it envisions an entirely new framework to provide adequate privacy protections. Chapter Three of the report discusses increasing threats to privacy as "the amount of information about individuals that is publicly available has grown and the technology that can permit unauthorized re-identification has improved."[812] It notes that forming solutions to this problem while preserving the quality of data is difficult, and that a challenge is "ensuring that enhanced statistical disclosure methods do not change the data in ways that increase the difficulty of reproducing research results." It thus specifically notes that protecting confidentiality can be in tension with allowing data to be used for reproducibility purposes.

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[808] *Id.* at 62.
[809] *Id.*
[810] 83 Fed. Reg. at 18,771.
[811] Commission on Evidence-Based Policymaking, *The Promise of Evidence-Based Policymaking* (2017).
[812] *Id.* at 54-55.

The report recommends: (1) amending federal statutes to require Federal departments to conduct a comprehensive risk assessment on de-identified confidential data intended for public release and release de-identified confidential data subject to the Privacy Act and CIPSEA only after a disclosure review board approves the release and publicly provides the risk assessment and a description of steps taken to mitigate risk; (2) federal departments to adopt state-of-the-art database, cryptography, privacy-preserving, and privacy-enhancing technologies for confidential data used for evidence building; (3) federal departments assign a senior official the responsibility for coordinating access to and stewardship of the department's data resources; (4) new legislation ensuring that data acquired under a pledge of confidentiality are kept confidential and used exclusively for statistical purposes.[813] The Proposal does not discuss or contribute to any of these efforts.

Chapter Four recognizes that some data cannot be made publicly available without sacrificing the utility of the evidence and thus sets forth recommendations for creating a new National Secure Database Service to allow researchers to access "detailed data that cannot be made publicly available, and only for exclusively statistical purposes."[814] This report thus implicitly recognizes the value of using confidential data to "securely generate evidence about government policies and programs."[815] While transparency is a crucial goal, using data that cannot be made publicly available can help inform government policies in important ways.

The Report details the many obstacles to making data publicly available, and ultimately concludes that much more work is needed in this area, none of which is being furthered by EPA's Proposal.

II. NAS, Innovations in Federal Statistics: Combining Data Sources While Protecting Privacy (2017)

This report provides recommendations to increase sharing and use of data by the federal government and between agencies.[816] It places maintaining privacy and confidentiality at the forefront. The report provides a discussion of the benefits and challenges to allowing external researchers to access data held by government agencies. This assumes that agency has access to data in the first place—which may not be the case with the studies EPA wishes to rely on that would be barred by its Proposal.

The report notes multiple risks to privacy and confidentiality from data breaches, identity theft, and the threat from the ability to combine multiple data sources to re-identify anonymized data as more and more data is made publicly available.[817] The solutions that the report proposes to minimize these risks include: data minimization, restricted data, restricted access (including licensing agreements, federal statistical research data centers, nongovernment data enclaves).[818]

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[813] *Id.* at 47.
[814] *Id.* at 66.
[815] *Id.* at 68.
[816] NAS, *Innovations in Federal Statistics: Combining Data Sources While Protecting Privacy*, National Academies Press (2017).
[817] *Id.* at 76-79.
[818] *Id.* at 82-88.

The Proposal does not allow for data minimization since it is aimed at making public complete underlying data that is likely to involve salient personally identifiable information for an unlimited amount of time.[819] Data restriction involves "removing explicit identifiers and applying a variety of statistical disclosure limitation methods to the dataset to reduce the risk of disclosure."[820] However, because these techniques "decrease the precision of the variables in the dataset and. . . introduce errors" it is unclear that they would preserve data for independent validation while also sufficiently protecting privacy.[821] Restricted access involves using "administrative procedures and technology to restrict who can access the dataset and what kinds of analyses can be done with the data to reduce the risk of disclosure."[822] This specifically limits access to data from the general public, which seemingly would not meet the requirements of EPA's proposal. Thus, EPA has not addressed how it would meet any of the challenges raised in this document.

III. NAS, Federal Statistics, Multiple Data Sources, and Privacy Protection: Next Steps (2017)

This report is not directly relevant as it discusses ways to combine diverse data sources from government and private sector sources and the privacy issues that arise from combining multiple data sets.[823] The purpose of the report is to help "federal statistical agencies examine and evaluate data from alternative sources and then combine them as appropriate to provide the country with more timely, actionable, and useful information for policy makers, businesses, and individuals."[824] EPA's proposal will in fact restrict the information that EPA can use.

The report notes that the "privacy status of data is dynamic over time, that datasets that are not individually identifiable today may in the future become individually identifiable" with the availability of new techniques and auxiliary data. [825] It notes that as data sets are linked, these privacy threats increase.[826] The Proposal does not discuss or address threats to privacy from data linkages.

The panel highlighted a number of threats to privacy and data security, including from security threats and inferential disclosure, and concluded "there is awareness of weaknesses of current statistical disclosure limitation methods, but the feasibility for federal statistical agencies of implementing new technologies, such as differential privacy, has not been clearly demonstrated."[827] Finally, they state:

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[819] *Id.* at 82-83.
[820] *Id.* at 83.
[821] *Id.*
[822] *Id.* at 85.
[823] NAS, *Federal Statistics, Multiple Data Sources, and Privacy Protection: Next Steps*, National Academies Press (2017).
[824] *Id.* at 2.
[825] *Id.* at 71.
[826] *Id.* at 72.
[827] *Id.* at 105.

> Overall, much work, interaction, and collaboration will be needed across the various disciplines and stakeholders as agencies seek to move forward to provide stronger privacy protection for the data they either collect from respondents or acquire access to from other administrative and private-sector sources for statistical purposes. It will be critical for there to be robust discussions of the implications of this approach for all stakeholders and these discussions will need to be informed by concrete examples to help everyone understand how use of these technologies will affect them.[828]

The report notes that in order to provide greater access to data much more research and resources are needed. The Proposal identifies no such resources or processes needed to develop needed methods and techniques to allow for greater data disclosure.

Footnote 20: For example, see policies or recommendations of publishers Taylor & Francis, Elsevier, PLOS, and Springer Nature

EPA cites to "policies or recommendation" of several journals that require data be deposited in public data repositories as an example of the Proposal's requirement of data availability.[829] EPA provided only a list of journals with no reference to any specific policies making it difficult to respond fully to this statement.

Each of these journals, however, has exceptions to its data availability requirements when there are valid reasons preventing authors from making their data publicly available via a public data repository. Further, the editors of these journals released a joint statement that explains why their policies with regards to data availability should not be used to support a policy by a federal agency that would in fact restrict the scientific studies it could rely on.[830] Given the vastly different contexts and aims of federal agencies and scientific journals when it comes to making data publicly available, journal policies should not inform EPA's direction. None of these journals claims that lack of data availability in itself calls into question the validity of a scientific conclusion based on that data—and thus these policies do not support the Proposal.

Footnote 21: For example: https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/; https://www.census.gov/fsrdc

As examples of controlled access to data in federal research data centers, EPA cites to the National Institutes of Health's policy for requesting access to controlled-access data maintained in NIH-designated data repositories and the U.S. Census Bureau's website on Federal Statistical Research Data Centers, secure facilities providing authorized access to restricted-use microdata for statistical purposes only. NIH requires researches to be a tenure-track professor, senior

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[828] *Id.* at 106.
[829] 83 Fed. Reg. at 18,771.
[830] Jeremy Berg et. al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

scientist, or equivalent and go through required procedures prior to gaining access.[831] The U.S. Census Bureau requires researchers to obtain Census Bureau Special Sworn Status, which requires passing a moderate risk background check and swearing to protect respondent confidentiality for life, with significant financial and legal penalties under Title 13 and Title 26 for failure to do so.[832]

It is unclear how these policies are informing EPA's proposal. EPA's proposal would require data to be made "publicly available," and these forms of restricted access specifically do not make data publicly available. They require significant resources and infrastructure and careful thought about who will be permitted to access such data and under what conditions—none of which EPA has provided any discussion of in the Proposal.

Footnote 22: These recommendations are consistent with those of Lutter and Zorn (2016). https:// www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.we re.

EPA cites to a working paper by Randall Lutter and David Zorn as supporting the proposition that "EPA should collaborate with other federal agencies to identify strategies to protect confidential and private information in any circumstance in which it is making information publicly available. These strategies should be cost-effective and may also include: Requiring applications for access; restricting access to data for the purposes of replication, validation, and sensitivity evaluation; establishing physical controls on data storage; online training for researchers; and nondisclosure agreements."[833]

Lutter and Zorn reference these strategies as ones agencies could use to minimize the risks to personally identifiable information when agencies make data publicly available.[834] However, EPA's proposed regulations do not discuss or propose implementation of any of these strategies. The Proposal would result in a rule that mandates only that data be made "publicly available" without any possibility for more restricted release. As the comments discuss, EPA has further not consulted with other federal agencies on this Proposal.

Lutter and Zorn additionally do not argue that agencies should immediately disregard studies where data cannot be made publicly available, and provide alternative procedures agencies should utilize in those cases when still relying on studies.[835] In a separate statement on the HONEST Act, which contains similar requirements as the Proposal, Lutter and Zorn stated that the legislation "should also allow agencies to regulate in instances where they do not possess data."[836] While these additional procedures they recommend agencies follow could still be overly

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[831] NIH, *Requesting Access to Controlled-Access Data Maintained in NIH-Designated Data Repositories (e.g., dbGaP)*, https://osp.od.nih.gov/scientific-sharing/requesting-access-to-controlled-access-data-maintained-in-nih-designated-data-repositories-e-g-dbgap/ (last accessed Aug. 10, 2018).
[832] U.S. Census Bureau, *Secure Research Environment*, https://www.census.gov/about/adrm/fsrdc/about/secure_rdc.html (last accessed Aug. 10, 2018).
[833] 83 Fed. Reg. at 18,771.
[834] Randall Lutter & David Zorn, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, Mercatus Working Paper 31 (Sept. 2016).
[835] *Id.* at 32-33.
[836] Randall Lutter and David Zorn, *The Data That Our Government Uses Must be Transparent*, SmartRegs (Mar. 13, 2017), https://smartregs.org/the-data-that-our-government-uses-must-be-transparent-caa16b3dc19d.

burdensome and barriers to EPA promulgating important safeguards, it is important to note that even they see the dangers in a rule that would force the agency to disregard studies when underlying data could not be made public.

Footnote 23: https://www.nap.edu/catalog/11434/ expanding-access-to-research-data-reconciling-risks-and-opportunities.

The Proposal claims "The benefits EPA ensuring that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation are that it will improve the data and scientific quality of the Agency's actions and facilitate expanded data sharing and exploration of key data sets."[837] EPA cites to a National Academies report. This report does speak to many benefits of making data available to researchers, including helping to maintain and improve data quality;[838] promoting new research and exploration of new questions using existing data;[839] and allowing for verification, refutation, or refinement of original results.[840]

However, the report simply considers the benefits of making data publicly available in a broad sense, it does not consider the issue in the Proposal—which is that new data is not necessarily being made publicly available that was not before, and at the same time EPA's consideration of scientific research is being limited. Thus, it does not consider the costs to government policy-making that come from EPA's refusing to consider scientific research where underlying data is not publicly available. Since it is questionable whether the Proposal will result in any new data being made available to the public, and certain that it will result in EPA's ignoring valid scientific findings, it is unlikely that this Proposal will "improve the data and scientific quality of the Agency's actions" as EPA claims.

Footnote 24: https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf.

EPA cites to a paper by Randall Lutter and David Zorn for its analysis that ''an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available."[841] However, there are important limitation to this analysis that seriously call this conclusion into question.

First, the statement that EPA cites to is taken out of context. The entire sentence is: "More specifically, we can calculate an increase in existing net benefits from greater reproducibility, which, if it occurred, would cover the costs of obtaining the data and making the data available."[842] This statement is *not* a conclusion that the benefits of making publicly

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[837] 83 Fed. Reg. at 18,772.
[838] The National Academies, *Expanding Access to Research Data: Reconciling Risks and Opportunities*, National Academies Press 48 (2005).
[839] *Id.* at 38.
[840] *Id.* at 39.
[841] Randall Lutter & David Zorn, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, Mercatus Working Paper (Sept. 2016).
[842] *Id.* at 27.

available data underlying research that federal agencies use to promulgate significant public polices would outweigh the costs. It is describing the figure that Lutter and Zorn go on to calculate—the threshold level of increase in net benefits required by this policy to equal the costs of implementation. They find that "an improvement in net benefits of 0.02 to 2.08 percent would imply that the net benefits of requiring data access are positive."[843] They themselves note that this estimate "fall[s] short of proving that the benefits outweigh the associated costs."[844]

Their analysis itself is suspect because it differs greatly from the cost estimate provided by the Congressional Budget Office for H.R. 1430, Honest and Open New EPA Science Treatment Act of 2017. The CBO estimated that, if the agency were to choose to rely only on studies that met the Act's requirements from the outset, implementing this legislation would cost about $5 million from 2018-2022.[845] They assumed it would cost $10,000 per study to make data available to enable use of studies.[846] They estimated costs of at least $100 million per year if EPA were to continue to rely on as many studies to support its actions as it has done in recent years.[847] An older cost estimate from CBO on a prior version of the HONEST Act estimated that it would cost "about $250 million a year for the next few years."[848] This assumed that EPA would spend from $10,000 to $30,000 per study to make the data available and that EPA would reduce the number of studies it relies on by about one-half.[849]

Zutter and Lorn calculated an alternative amount for the costs to EPA of this legislation. They find that "the total cost to the EPA for data collection and public accessibility would be $2,558 per study, or about 26 percent of the $10,000 per study cost estimated by CBO."[850] They used estimates that EPA reported under the Paperwork Reduction Act for time that entities in the chemical industry would need to spend to comply with EPA's Health and Safety Data Reporting Rule (40 C.F.R. 716).[851] While they purport that the requirements of that rule are similar to the activities that EPA would undertake to comply with the HONEST Act and similar legislation, they provide no further basis for this.[852] Given the great discrepancy between their and CBO's estimates, it is unclear that their estimate sufficiently accounts for the numerous costs associated with EPA locating underlying research data not currently in its possession and upgrading it to enable it to be made publicly available.

They also rely on questionable assumptions in their calculation. They assume that "given modern technology, by the time research has been published, almost all relevant underlying data

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[843] *Id.*
[844] *Id.* at 29.
[845] Congressional Budget Office, *Cost Estimate: H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017* (Mar. 29, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf.
[846] *Id.* at 3.
[847] *Id.* at 3.
[848] Congressional Budget Office, *Cost Estimate: H.R. 1030 Secret Science Reform Act of 2015* (Mar. 11, 2015), https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf.
[849] *Id.* at 3.
[850] Randall Lutter & David Zorn, *On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making*, Mercatus Working Paper 23 (Sept. 2016).
[851] *Id.* at 21.
[852] *Id.*

and computer code and models will be in electronic format" so time spend photocopying studies will be reduced.[853] This does not consider that EPA may want to rely on older studies where all relevant information is not available in electronic, easily accessible formats. They provide unsupported estimates for activities that EPA would need to undertake to comply with HONEST Act-like legislation that has no corresponding requirement in EPA's Health and Safety Data Reporting Rule—such as estimating 10 hours for EPA to format unformatted data for public access.[854]

They additionally produce their own estimate for the number of studies that EPA relies on each year, looking at materials posted in dockets on regulations.gov and coming to a total of 18,000 pieces of scientific research per year.[855] CBO estimated 50,000 scientific studies per year.[856] Assuming that EPA continued to rely on all 18,000 studies per year, Zutter and Lorn came to total implementation costs of about $46 million per year, far below the estimate by CBO assuming EPA still relied on at least half of the studies it does currently. Thus, one should view this cost estimate with suspicion, and there is no reason it should be relied on over CBO's cost estimates and does not suffice for EPA providing its own cost benefit analysis.

May 25, 2018 Memorandum

On May 25, 2018, EPA provided a memorandum that provided additional hyperlinks for some of the sources cited in the footnotes.[857]

Footnote 9

- **National Science Foundation: https://www.nsf.gov/bfa/dias/policy/dmp.jsp**
- **National Institute of Science and Technology: https://www.nist.gov/open**
- **National Institutes of Health: https://grants.nih.gov/policy/sharing.htm**

The hyperlinks that EPA provides fail to point to any relevant policies that support EPA's Proposal. First, EPA links to the National Science Foundation's policies requiring investigators who receive NSF grants to share research data with other researchers.[858] Importantly, they are only to release privileged or confidential information "in a form that protects the privacy of individuals and subjects involved" and NSF may make adjustments or exceptions when needed

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[853] *Id.* at 22.
[854] *Id.*
[855] *Id.* at 24.
[856] Congressional Budget Office Cost Estimate: H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (Mar. 29, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1430.pdf. 3
[857] May 25, 2018 Memorandum Re: Omitted Hyperlinks for Footnotes in the Proposed Rule (Docket ID No. EPA–HQ–OA–2018–0259)
[858] NSF, *Disseminating and Sharing of Research Results*, https://www.nsf.gov/bfa/dias/policy/dmp.jsp (last accessed Aug. 10, 2018).

"to safeguard the rights of individuals and subjects, the validity of results, or the integrity of collections or to accommodate the legitimate interest of investigators."[859]

EPA links to the National Institute of Science and Technology policy on sharing data arising from NIST-funded research.[860] The plan clearly exempts "[p]ersonnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy" from being subject to the data sharing policy.[861]

EPA also cites to The National Institutes of Health. The hyperlink links to a webpage consisting of a number of policies dictating sharing of NIH-funded research with no clarification of which policy EPA is referring to or why it is relevant to the Proposal. While NIH policies do in many cases require data from NIG-funded research to be shared publicly—these policies place protection of personal information at the forefront and thus include controls such as controlled access, de-identification of information, data aggregation and allow exceptions when data cannot be made publicly available.

These examples all deal with policies to share data that the agencies have access to and the ability to share—because they deal with federally-funded research. EPA's Proposal, on the other hand, applies to all data whether or not EPA has the data in its possession or is authorized to release it. They all speak to making data available to increase its utility, not to making data available specifically for the purposes of independent validation of research results, which requires data be available on a more granular level that makes privacy protection more difficult. Further, EPA already has policies in place to make publicly available data that is produced by research it funds. Also, none of these policies address regulating how the agencies themselves rely on or use scientific information. Thus the Proposal in no way "builds upon" the efforts they represent.

Footnote 10

- **Administrative Conference of the United States' Science in the Administrative Process Project: https://www.acus.gov/research-projects/science-administrative-process**
- **Improving Access to and Confidentiality of Research Data: https://www.nap.edu/read/9958**
- **Expanding Access to Research Data: https://www.nap.edu/catalog/11434/expanding-access-to-research-data-reconciling-risks-and-opportunities**
- **Access to Research Data in the 21st Century: https://www.nap.edu/catalog/10302/access-to-research-data-in-the-21st-century-an-ongoing**
- **Health Effects Institute: https://www.healtheffects.org/system/files/AppendixD-data-access_3.pdf**

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[859] NSF, *Chapter XI - Other Post Award Requirements and Considerations*, https://www.nsf.gov/pubs/policydocs/pappg17_1/pappg_11.jsp#XID4 (Jan. 30, 2017).
[860] NIST, *Public Access to NIST Research*, https://www.nist.gov/open (last accessed Aug. 10, 2018).
[861] NIST, *Managing Public Access to Results of Federally Funded Research Policy* 1-2 (Jun. 26, 2015), https://www.nist.gov/sites/default/files/documents/2018/06/19/final_p_5700.pdf.

- **Center for Open Science: https://osf.io/x2w9h/?_ga=2.15543670.1160736397.1518527893-776332106.1518527893**
- **Members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology: http://www.isrtp.org/GMU%20WEBINAR_DEC_2013/GMU%20Study%20Document4.pdf**
- **Bipartisan Policy Center's Science for Policy Project: http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf**

I. The Health Effects Institute, https://www.healtheffects.org/system/files/AppendixD-data-access_3.pdf

EPA provides a link to the HEI Policy On The Provision Of Access To Data Underlying HEI funded Studies. This policy is "to provide access expeditiously to data for studies that it has funded and to provide that data in a manner that facilitates review and verification of the work but also protects the confidentiality of any volunteers who may have participated in the study and respects the intellectual interests of the original investigator of the work."[862] It is written to be consistent with OMB Circular A-110, which requires agencies to respond to FOIA requests for data underlying federally supported research used to develop federal agency actions with the force and effect of law. EPA already has policies in place to make public the data underlying research that it funds, and already must comply with OMB Circular A-110, thus, it is unclear how this Proposal builds upon this policy.

Furthermore, the policy specifically excludes "personal and medical information and similar information that is personally identifiable, and the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study" and requires the requestor to pay reasonable costs. In this manner, it further deviates from the Proposal.[863]

II. Center for Open Science, https://osf.io/x2w9h/?_ga=2.15543670.1160736397.1518527893-776332106.1518527893

EPA links to the Center for Open Science's 2017-2020 Strategic Plan.[864] While the strategic plan outlines COS's own mission to "increase openness, integrity, and reproducibility of scholarly research" and to meets its goal of creating "a future scholarly community in which the process, content, and outcomes of research are openly accessible by default" nothing in this

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[862] HEI, *APPENDIX D: HEI POLICY ON THE PROVISION OF ACCESS TO DATA UNDERLYING HEIFUNDED STUDIES*, https://www.healtheffects.org/system/files/AppendixD-data-access_3.pdf (last accessed Aug. 10, 2018).
[863] *Id.*
[864] Center for Open Science, *Strategic Plan*, https://osf.io/x2w9h/?_ga=2.15543670.1160736397.1518527893-776332106.1518527893.

strategic plan suggests anything like EPA's Proposal.[865] It does not discuss barring use of studies or ensuring access to underlying data—and thus is completely irrelevant to the Proposal.

III. Members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology: http://www.isrtp.org/GMU%20WEBINAR_DEC_2013/GMU%20Study%20Document4.pdf

EPA links to a survey conducted by the Center for Media and Public Affairs and Center for Health and Risk Communication at George Mason University.[866] They surveyed members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology. However, the survey thus does not represent any official recommendation or policy position from these professional organizations, and represent only the views of the members who chose to participate in the survey.

Thus, while the survey found 69 % of those surveyed "regard it as "very important" for assessors to have access to underlying raw data for the most critical studies in order to independently analyze their results," this should be viewed in the rightful context.[867] The survey did not ask whether agencies should continue to rely on scientific studies where the underlying data cannot be made public or independently analyzed. The survey question further appears to have only asked whether researchers assessing studies should have access to underlying data to independently analyze results, not whether underlying data should be made *publicly available*.

Further, the Dose Response Section of the Society for Risk Analysis has since submitted a comment to EPA that states this footnote and the claim that EPA makes that the Proposal took into consideration these recommendations and policies is "inaccurate" and that "the 'Dose-Response Section [sic] of the Society for Risk Analysis' has never adopted any 'policies or recommendations' on this or any other topic."[868] They have asked that EPA remove all references to the organization and make clear in the comment response for this rule that "'third party Organizations' whose policies and recommendations were considered do not include the Society for Risk Analysis or the Dose-Response Specialty Section."

The Society for Toxicology similarly have said this survey does not constitute support from the Specialty Section or the SOT as a whole, and requesting "that any and all references to "members of the Risk Assessment Specialty Section of the Society of Toxicology" be removed

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[865] *Id.* at 6.
[866] George Mason University, *Expert Opinion on Regulatory Risk Assessment* (Dec. 6, 2013), http://www.isrtp.org/GMU%20WEBINAR_DEC_2013/GMU%20Study%20Document4.pdf.
[867] Id. at 2-3.
[868] Comment from Weihsueh A. Chiu, Chair, Dose-Response Specialty Group, Society for Risk Analysis, Docket ID No. EPA–HQ–OA–2018–0259 (May 24, 2018).

from the Final Rule."[869] They also specifically comment that "invalidating data solely on the basis of public availability is inappropriate."[870]

IV. Bipartisan Policy Center's Science for Policy Project, http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf

EPA provides a hyperlink to the Final Report of the Science for Policy Project *Improving the Use of Science in Regulatory Policy*.[871] This report makes a number of recommendations, none of which endorse the Proposal. In relevant part, Recommendation Three suggests "Agencies and their scientific advisory committees should cast a wide net in reviewing studies relevant to regulatory policy, and should make their methods for filtering and evaluating those studies more transparent."[872] They urge agencies to increase availability of data and information on research studies and subject all studies relied on in the formulation of regulation to be subject to the requirements of the Shelby Amendment and OMB Circular A-110 regardless of who funded the study.[873] Importantly, those requirements contain important exception for confidentiality and privacy concerns—and thus do not support the Proposal.

This recommendation is also aimed at *increasing* use of science in regulatory policy, and does not suggest that agencies not rely on studies where those data access requirements cannot be met because of other concerns. It also highlights that the use of CBI to prevent access to data appears to be overused and urges agencies to make procedures more stringent to allow only for legitimate claims of CBI—which EPA does not address in its Proposal.[874]

Recommendation Four states: "The federal government, universities, scientific journals and scientists themselves can help improve the use of science in the regulatory process by strengthening peer review, expanding the information available about scientific studies, and setting and enforcing clear standards governing conflict of interest."[875] As part of this recommendation, the report "Federal agencies, universities and journals should encourage or require on-line publication of the methods and data underlying published scientific studies."[876] However, it once again does not say that agencies should not consider research studies where this is not possible due to privacy or other compelling reasons.

Wendy Wagner, who served on the panel that produced the recommendations has stated: "They don't adopt any of our recommendations, and they go in a direction that's completely

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[869] Comment from Leigh Ann Burns Naas, Society of Toxicology, Docket ID No. EPA–HQ–OA–2018–0259 (May 25, 2018) at 1.
[870] *Id.* at 2
[871] Bipartisan Policy Center, Science for Policy Project, *Improving the Use of Science in Regulatory Policy* (Aug. 5, 2009), http://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf.
[872] *Id.* at 41.
[873] *Id.*
[874] *Id.* at 43.
[875] *Id.* at 45.
[876] *Id.* at 46.

opposite, completely different. . . . They don't adopt any of the recommendations of *any* of the sources they cite. I'm not sure why they cited them."[877]

Footnote 11

- **Proceedings of the National Academy of Sciences: http://www.pnas.org/page/authors/journal-policies#xi**
- **PLOS ONE: http://journals.plos.org/plosone/s/data-availability**
- **Science: http://www.sciencemag.org/authors/science-journals-editorial-policies**
- **Nature: http://www.nature.com/authors/policies/data/data-availability-statements-data-citations.pdf**

While EPA links to journal policies that encourage or require, in some instances, sharing data, they contain exceptions when privacy would be compromised.[878] The editors of these journals issued a joint statement opposing the Proposal. They note that some data sets cannot be shared publicly, and that there are still other methods available to verify scientific findings. The statement also strongly condemns the notion of excluding scientific information from consideration when underlying data cannot be made publicly available:

> It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes.[879]

Thus, journal policies encouraging the sharing of underlying data do not support a proposal by a regulatory agency to exclude from consideration studies when the underlying data is not publicly available.

Footnote 16:

- **U.S. Department of Health and Human Services: https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html**
- **National Institute of Standards and Technology: https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf**
- **U.S. Department of Education: https://studentprivacy.ed.gov/sites/default/files/resource_document/file/data_deidentification_terms.pdf**
- **U.S. Census Bureau: https://www.census.gov/about/adrm/linkage/technical-documentation/processing-de-identification.html**

EPA suggests the examples linked to could address concerns about privacy and confidentiality arising from the Proposal. However, the cited sources provide no assurance that

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[877] Robinson Meyer, *Scott Pruitt's New Rule Could Completely Transform the EPA*, The Atlantic (Apr. 25, 2018), https://www.theatlantic.com/science/archive/2018/04/how-the-epas-new-secret-science-rule/558878/.

[878] *See* discussion below on footnote 20.

[879] Jeremy Berg et. al., *Joint statement on EPA proposed rule and public availability of data*, Science (Apr. 30, 2018), http://science.sciencemag.org/content/early/2018/04/30/science.aau0116.

the Proposal could be implemented to expand disclosure of personal data without serious risks to privacy.

I. U.S. Department of Health and Human Services, https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

EPA first points to guidance on de-identification requirements under HIPAA. This guidance provides two methods for de-identifying data: (1) expert determination method, where an expert determines that, after application of statistical and scientific principals and methods, the risk is very small that the information alone or with other available information could be used to identify the subject; and (2) the safe harbor method, requiring that a number of identifiers are removed. The first method requires case-by-case work and EPA has provided no information regarding how EPA could implement it or how much it might cost and thus the feasibility of requiring researchers or EPA to de-identify data this way is questionable. The second method requires removal of much information useful for research that may be necessary to be able to independently validate the research, so it is unclear that it would satisfy the Proposal's demands. Furthermore, the safe harbor method has been shown to provide potentially insufficient privacy protections.[880]

II. National Institute of Standards and Technology, https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf

EPA links to a NIST document entitled *De-Identification of Personal Information* as a potential solution to address concerns about confidentiality and privacy.[881] This document discusses different techniques and issues with de-identification of personal information. However, the document does not discuss de-identification of personal information specifically for the purposes of making research data publicly available for independently validating scientific studies. The document instead notes that:

> The purpose of de-identifying data is to allow some uses of the de-identified data while providing for some privacy protection by shielding the identity of the data subjects. These two goals are antagonistic, in that there is a trade-off between the amount of de-identification and the utility of the resulting data. However, de-identification opens up new uses for the data that were previously prohibited due to privacy concerns. It is thus the role of the data controller, standards bodies, regulators, lawmakers and courts to determine the appropriate level of security, and thereby the acceptable trade-off between de-identification and utility.[882]

EPA completely fails to note this obstacle, that as data is stripped of identifiable material it also loses utility to researchers. EPA cites to broad privacy protection techniques without explaining

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[880] Latanya Sweeney, Ji Su Yon, Laura Perovich, Katherine E Boronow, Phil Brown, and Julia Green Brody, *Re-identifcation Risks in HIPAA Safe Harbor Data: A Study of Data From One Environmental Health Study*, Technology Science (August 28, 2017).
[881] Simson L. Garfinkel, *De-Identification of Personal Information* (NISTIR 8053), NIST (Oct. 2015), https://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf.
[882] *Id.* at 11-12.

whether they could be applied to protect privacy while still allowing enough utility in the data set to allow for independent validation as required by the Proposal.

The document notes many of the challenges to protecting privacy including that: "de-identification approaches based on suppressing or generalizing specific fields in a database cannot provide absolute privacy guarantees, because there is always a chance that the remaining data can be re-identified using an auxiliary dataset."[883] The harms of data linkages and increasing difficulty to preserve privacy as more and more information about individuals is made available is another challenge that EPA has not addressed.

III. U.S. Department of Education, https://studentprivacy.ed.gov/sites/default/files/resource_document/file/data_deidentification_terms.pdf

EPA links to a document of the Privacy Technical Assistance Center, *Data De-identification: An Overview of Basic Terms*, which provides a high-level overview of key terms and practices to help educational agencies and institutions comply with the Family Educational Rights and Privacy Act (FERPA).[884] EPA has not explained why the requirements of FERPA are applicable here. This document is concerned with data disclosure that occurs "when schools, districts, or states publish reports on student achievement or share students' data with external researchers" not to make information publicly available for independent validation.[885] Thus its unclear that methods used to de-identify but preserve data for those purposes would be adequate in this context.

For example, one of the methods that the U.S. Department of Education uses for disclosure avoidance for tabular data is to not release information for any cell that has a size below some minimum, which essentially means not disclosing information where there are small numbers in a certain cell.[886] This could obviously lead to a loss of information that would prevent a de-identified data set from being used to independently validate research findings.

IV. U.S. Census Bureau, https://www.census.gov/about/adrm/linkage/technical-documentation/processing-de-identification.html

EPA provides a link to a website titled *Data Ingest and Linkage* that details the U.S. Census Bureau's approach to linking data across many records held by the Bureau, permitting more detailed information to be linked back to one individual to allow for analysis and research. The website links to a working paper that describes the method by which the Bureau assigns a unique person identifier to records it holds that enables it to link records together to create the

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[883] *Id.* at 5.
[884] U.S. Department of Education, Privacy Technical Assistance Center, *Data De-identification: An Overview of Basic Terms* (Oct. 2012), https://studentprivacy.ed.gov/sites/default/files/resource_document/file/data_deidentification_terms.pdf.
[885] *Id.*
[886] *Id.* at 4.

final file.[887] It is totally unclear how this process on linking together records is a solution that EPA could implement to protect privacy of individuals when disclosing data as it concerns how to identify data to specific people—not how to make data available while protecting their privacy.

Footnote 20:

- Taylor & Francis: https://authorservices.taylorandfrancis.com/data-repositories/
- Elsevier: https://www.elsevier.com/authors/author-services/research-data
- PLOS: http://journals.plos.org/plosone/s/data-availability
- Springer Nature: https://www.springernature.com/gp/authors/research-data-policy/repositories

EPA cites to "policies or recommendation" of several journals that require data be deposited in public data repositories as an example of the Proposal's requirement of data availability.[888] While these journals have policies that encourage authors to deposit data in public data repositories, they all have important exceptions in cases where this is not feasible or ethical.

The hyperlink for Taylor & Francis links to a page that provides information about how to find public data repositories to submit date to in order to comply with journal sharing policies. However, Taylor & Francis' basic data sharing policy "which applies across many of [their] journals" does not *require* data be submitted to a public data repository, but "encourages authors to share and make data open where this does not violate protection of human subjects or other valid subject privacy concerns."[889] Thus, this policy is flexible and allows exceptions for when privacy concerns are at stake.

The hyperlink for Elsevier links to a page providing general information about data sharing. While the web page notes that researchers "are increasingly encouraged, or even mandated, to make. . . research data available, accessible, discoverable and usable," it also provides important qualifications.[890] It notes, "there are times when the data is simply not available to post or there are good reasons why it shouldn't be shared."[891] In these cases, authors are encouraged to provide a data statement explaining why the data cannot be shared.

The hyperlink for PLOS links to a page describing PLOS's data availability policies. It explains, "PLOS journals require authors to make all data underlying the findings described in their manuscript fully available without restriction, with rare exception."[892] The policy recommends deposition of the data into a public repository, however, it recognizes that there are

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[887] Deborah Wagner & Mary Layne, *The Person Identification Validation System (PVS): Applying the Center for Administrative Records Research and Applications' (CARRA) Record Linkage Software, CARRA Working Paper Series*, Working Paper # 2014-01, U.S. Census Bureau (July 1, 2014).
[888] 83 Fed. Reg. at 18,771.
[889] Taylor & Francis Author Services, *Understanding our data sharing policies*, https://authorservices.taylorandfrancis.com/understanding-our-data-sharing-policies/ (last accessed Aug. 10, 2018).
[890] Elsevier, *Sharing research data*, https://www.elsevier.com/authors/author-services/research-data (last accessed Aug. 10, 2018).
[891] *Id.*
[892] PLOS One, *Data Availability*, http://journals.plos.org/plosone/s/data-availability (last accessed Aug. 10, 2018).

instances when this may not be ethical or legal, for instance because the "underlying data pose privacy or legal concerns e.g., where data might reveal the identity or location of participants."[893] In these instances, it allows an exception to this policy.

The hyperlink for Springer Nature links to a page listing recommended repositories. While Springer Nature's data policies support data sharing via public data repositories, it notes, "reasonable restrictions on data availability are permitted to protect human privacy, biosafety or respect reasonable terms of use for data obtained under license from third parties."[894]

[893] *Id.*

[894] Springer Nature, *Research Data Policies FAQs*, https://www.springernature.com/gp/authors/research-data-policy/faqs/12327154 (last accessed Aug. 10, 2018).

Appendix B. Provisions of Federal Environmental Statutes Requiring EPA to Consult With Other Federal Agencies in Implementing Key Programs

Consultation Provisions in Clean Air Act

Section	Section Title	Consultation Requirement
§118(c)	President's Air Quality Advisory Board and Advisory Committees	(c) Prior to- (1) issuing criteria for an air pollutant under section 108(a)(2) (2) publishing any list under section 111(b)(1)(A) or 112(b)(1)(A), (3) publishing any standard under section 111 or section 112, or (4) publishing any regulation under section 202(a), The administrator shall, to the maximum extent practicable within the time provided, consult with appropriate advisory committees, independent experts, and Federal departments and agencies.
§103	Research, Investigation, Training, and other Activities	Consult with other Federal agencies to coordinate research and avoid duplication of activities
§108(a)	Air Quality Criteria and Control Techniques	Consult with Federal agencies to issue information on air pollution control techniques
§108(c)	Air Quality Criteria and Control Techniques	"[A]fter consultation with the Secretary of Transportation…update the June 1978 Transportation-Air Quality Planning Guidelines and publish guidance on the development and implementation of transportation and other measures necessary to demonstrate and maintain attainment of national ambient air quality standards."
§108(f)(1)	Air Quality Criteria and Control Techniques	Consult with Secretary of Transportation to provide information "regarding the formulation and emission reduction potential of transportation control measures related to criteria pollutants and their precursors."
§112(d)(9)	Hazardous Air Pollutants	Allows Administrator not to list radionuclide emissions if Administrator determines, after consultation with Nuclear Regulatory Commission (NRC), that NRC regulations already provide an adequate margin of safety.
§122	Listing of Certain Unregulated Pollutants	Consult with NRC before listing any nuclear or nuclear by-product material
§169A	Visibility Protections for Federal Class 1 Areas	Consultation with Department of Interior and Federal Land Managers for regional haze determinations
§231(a)(2)(B)(i)	Aircraft Emission Standards	Consult with Federal Aviation Administration on aircraft engine emission standards
§250 (d)	General Provisions	Consult with Department of Energy (DOE) and Department of Transportation (DOT) in carrying out Administrator's duties under the this part (Clean Fuel Vehicles)
§404(f)(1)(A)	Energy Conservation and Renewable Energy	Consult with Secretary of Energy to determine Qualified Energy Conservation Measure

§507(b)(3)(A)	Small Business Stationary Source Technical and Environmental Compliance Assistance Program	Consult with SBA Administrator to determine which category of small business sources could be exempted

Consultation Provisions in Clean Water Act

Section	Section Title	Text
§304(c)	Information and Guidelines	Consult with appropriate Federal and State agencies to issue information on pollution-reducing procedures and operating methods to implement standards of performance under §306.
§304(d)(1)-(2)	Information and Guidelines	Consult with appropriate Federal and State agencies to publish the amount of reduction attainable through secondary treatment and information on alternative waste treatment management techniques.
§304(e)	Information and Guidelines	Consult with appropriate Federal and State agencies to publish supplemental regulations to control plant site runoff, leaks/spillage, sludge/waste disposal, and drainage
§304(f)	Information and Guidelines	Consult with Federal and State agencies to issue guidelines for evaluating nonpoint sources and methods to control pollution from those sources.
§307(a)(7)	Toxic Pretreatment Effluent Standards	Consult with Federal departments and agencies prior to publishing regulations pursuant to this section
§404(d)(1)	Disposal of Sewage Sludge	Administrator must consult with Federal agencies on regulations providing guidelines for the disposal of sludge and the utilization of sludge for various purposes.
§118(a)	Lake Tahoe Study	Coordinate with Secretary of Agriculture and other Federal agencies regarding adequacy and need for extending Federal oversight of Lake Tahoe
§311(d)(2)(M)	Oil and Hazardous Substance Liability	Consultation with FWS and NOAA for a fish and wildlife response plan
§312(e)	Marine Sanitation Devices	"Before the standards and regulations under this section are promulgated, the Administrator and the Secretary of the department in which the Coast Guard is operating shall consult with the Secretary of State; the Secretary of Health, Education, and Welfare; the Secretary of Defense; the Secretary of the Treasury; the Secretary of Commerce; other interested Federal agencies…."

Consultation Provisions in Federal Insecticide, Fungicide, and Rodenticide Act

Section	Section Title	Text
136w(a)(2)(A)	Authority of the Administrator: Procedure: Proposed regulations	**(A) Proposed Regulations:** **At least 60 days prior to signing any proposed regulation for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation.** If the Secretary comments in writing to

		the Administrator regarding any such regulation within 30 days after receiving it, the Administrator shall publish in the Federal Register (with the proposed regulation) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 30 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register any time after such 30-day period notwithstanding the foregoing 60-day time requirement.
136w(a)(2)(B)	Authority of the Administrator: Final Regulations	**At least 30 days prior to signing any regulation in final form for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation.** If the Secretary comments in writing to the Administrator regarding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register (with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement. In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect of the regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect
136w(a)(3)	Authority of the Administrator: Procedure: Congressional Committees	At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.
136w(a)(4)	Authority of the Administrator	Simultaneously with the promulgation of any rule or regulation under this subchapter, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

136w-3	Identification of Pests; cooperation with Department of Agriculture	The Administrator, in coordination with the Secretary of Agriculture, shall identify those pests that must be brought under control. The Administrator shall also coordinate and cooperate with the Secretary of Agriculture's research and implementation programs to develop and improve the safe use and effectiveness of chemical, biological, and alternative methods to combat and control pests that reduce the quality and economical production and distribution of agricultural products to domestic and foreign consumers.
136(r)(a)	Research and Monitoring: Research	The Administrator shall undertake research including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this subchapter, and **the Administrator shall conduct research into integrated pest management in coordination with the Secretary of Agriculture.** The Administrator shall also take care to ensure that such research does not duplicate research being undertaken by any other Federal agency.
136a-1(n)(2)-(3)	Reregistration of registered pesticides: Authorization of funds to develop public health data	**(2)** Consultation. In the case of a pesticide registered for use in public health programs for vector control or for other uses the Administrator determines to be human health protection uses, the Administrator shall, upon timely request by the registrant or any other interested person, or on the Administrator's own initiative may, consult with the Secretary [of Health and Human Services] prior to taking final action to suspend registration under section 3(c)(2)(B)(iv) or cancel a registration under section 4, 6(e), or 6(f). In consultation with the Secretary, the Administrator shall prescribe the form and content of requests under this section. **(3)** Benefits to support family. The Administrator, after consulting with the Secretary, shall make a determination whether the potential benefits of continued use of the pesticide for public health or health protection purposes are of such significance as to warrant a commitment by the Secretary to conduct or to arrange for the conduct of the studies required by the Administrator to support continued registration under section or reregistration under section 4
7 USCS 136(ll)(2)	Definitions: Minor Use	(2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and--

136i(a)(1)	Use of restricted use pesticides; applicators	Requires the Administrator to consult with Governor of each state to conduct a program for the certification of use of specific pesticides.
136a(c)(1)(F)(ii)	Registration of Pesticides: Procedure for registration	The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause [enacted Aug. 3, 1996] and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in **consultation** with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that--(I) there are insufficient efficacious alternative registered pesticides available for the use; (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health; (III) the minor use pesticide plays or will play a significant part in managing pest resistance; or (IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.
136t(b)	Delegation and Cooperation	**(b)** Cooperation. The Administrator shall cooperate with the Department of Agriculture, any other Federal agency, and any appropriate agency of any State or any political subdivision thereof, in carrying out the provisions of this Act and in securing uniformity of regulations.
136o(e)	Imports and Exports	Secretary of the Treasury shall prescribe regulations for this section in consultation with the Administrator.
136p	Exemption of Federal and State Agencies	The Administrator may, at the Administrator's discretion, exempt any Federal or State agency from any provision of this Act if the Administrator determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.
136w-7	Department of Agriculture Minor Use Program	**(A)** Grant authority. The Secretary, in consultation with the Administrator, shall establish a program to make grants for the development of data to support minor use pesticide registrations and reregistrations. The amount of any such grant shall not exceed 1/2 of the cost of the project for which the grant is made.
136i-1(a)(1)	Pesticide Recordkeeping	The Secretary of Agriculture, in consultation with the Administrator of the Environmental Protection Agency, shall require certified applicators of restricted use pesticides
136i-2(c)	Collection of Pesticide Use Information	Coordination. The Secretary of Agriculture shall, as appropriate, coordinate with the Administrator of the Environmental Protection Agency in the design of the

		surveys and make available to the Administrator the aggregate results of the surveys to assist the Administrator.

Consultation provisions under the Toxic Substances Control Act

Section	Title	Text
2609(a)	Research, Development, collection, dissemination, and utilization of data	**(a)** Authority. **The Administrator shall, in consultation and cooperation with the Secretary of Health and Human Services and with other heads of appropriate departments and agencies, conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act**. The Administrator may enter into contracts and may make grants for research, development, and monitoring under this subsection. Contracts may be entered into under this subsection without regard to sections 3648 and 3709 of the Revised Statutes
2609(b)(1), (2)	Research, development, collection, dissemination, and utilization of information: Information Systems	Administrator shall Consult and cooperate with Secretary of HHS and other heads of appropriate departments and agencies, to establish an efficient system for retrieval of toxicological and other scientific information which could be useful
2609(c)	Research, development, collection, dissemination, and utilization of information: Screening Techniques	Administrator shall coordinate with Assistant Secretary for HHS to develop screening techniques
2609(d)	Research, development, collection, dissemination, and utilization of information: Monitoring	Administrator shall, in consultation and cooperation with the Secretary of Health and Human Services, establish and be responsible for research aimed at the development, in cooperation with local, State, and Federal agencies, of monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures and which are reliable, economical, and capable of being implemented under a wide variety of conditions
2609(e)	Research, development, collection, dissemination, and utilization of information: Basic Research	The Administrator shall, in consultation and cooperation with the Secretary of Health and Human Services, establish research programs to develop the fundamental scientific basis of the screening and monitoring techniques described in subsections (c) and (d), the bounds of the reliability of such techniques, and the opportunities for their improvement.
2609(g)	Research, development, collection, dissemination, and utilization of information: Exchange of research and development results	The Administrator shall, in consultation with the Secretary of Health and Human Services and other heads of appropriate departments and agencies, establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard information format and analysis and consistent testing procedures.

2608(d)	Coordination	"Coordination. In administering this Act [15 USCS §§ 2601 et seq.], the Administrator shall consult and coordinate with the Secretary of Health and Human Services and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act . . ."
2608(e)	Exposure Information	If the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.
2604(f)(5)	Manufacturing and Processing Notices: Protection Against Unreasonable Risks	Consult with Assistant Secretary of Labor prior to adopting any restriction of chemical substance for workplace exposures
2604(h)(2)(B)(ii)	Manufacturing and Processing Notices: Exemptions	Consult with AG of the Federal Trade Commission about exempting persons from information requirements.

Consultation Provisions in the Safe Drinking Water Act

Section	Title	Text
300g-1 (b)(1)(D)	Standards: Listing of Contaminants for Consideration, Urgent Threats to Public Health	The Administrator may promulgate an interim national primary drinking water regulation for a contaminant without making a determination for the contaminant under paragraph (4)(C), or completing the analysis under paragraph (3)(C), to address an urgent threat to public health as determined by the Administrator after consultation with and written response to any comments provided by the Secretary of Health and Human Services, acting through the director of the Centers for Disease Control and Prevention or the director of the National Institutes of Health.
300g-1(d)	Regulations:	Regulations; public hearings; administrative consultations. Regulations under this section shall be prescribed in accordance with section 553 of title 5, United States Code (relating to rule-making), except that the Administrator shall provide opportunity for public hearing prior to promulgation of such regulations. In proposing and promulgating regulations under this section, the Administrator shall consult with the Secretary and the National Drinking Water Advisory Council.
300j-12(i)(2)	Funds: Indian Tribes: Use of Funds	(2) Use of funds. Funds reserved pursuant to paragraph (1) shall be used to address the most significant threats to public health associated with public water systems that serve Indian Tribes, as determined by the Administrator in consultation with the Director of the Indian Health Service and Indian Tribes.
300j-13(a)(5)	Source Water Quality Assessment	Demonstration project. The Administrator shall, as soon as practicable, conduct a demonstration project, in consultation with other Federal agencies, to demonstrate the most effective and protective means of

		assessing and protecting source waters serving large metropolitan areas and located on Federal lands.
300j-5(b)	National Drinking Water Advisory Council	**(b)** Functions. The Council shall advise, consult with, and make recommendations to, the Administrator on matters relating to activities, functions, and policies of the Agency under this title [42 USCS §§ 300f et seq.].
300j-3d	Water Supply Cost Savings	**(a)** Drinking water technology clearinghouse. The Administrator, in consultation with the Secretary of Agriculture, shall— **(1)** develop a technology clearinghouse for information on the cost-effectiveness of innovative and alternative drinking water delivery systems, including wells and well systems; and **(2)** disseminate such information to the public and to communities and not-for-profit organizations seeking Federal funding for drinking water delivery systems serving 500 or fewer persons.
300i-3(a)	Contaminant Prevention, Detection and Response	In general. The Administrator, in consultation with the Centers for Disease Control and, after consultation with appropriate departments and agencies of the Federal Government and with State and local governments, shall review (or enter into contracts or cooperative agreements to provide for a review of) current and future methods to prevent, detect and respond to the intentional introduction of chemical, biological or radiological contaminants into community water systems and source water for community water systems, including each of the following:
300j-19(b)(2)(A)	Algal Toxin Risk Assessment and Management	(b) Information coordination. In carrying out this section the Administrator shall-- (2) as appropriate, consult with-- • (A) other Federal agencies that-- o (i) examine or analyze cyanobacteria or algal toxins; or o (ii) address public health concerns related to harmful algal blooms;

Consultation Provisions in the Comprehensive Environmental Response, Compensation, and Liability Act

Section	**Section Title**	**Consultation Requirement**
§311(a)(1)	Research, Development, and Demonstration	The Secretary of Health and Human Services…in consultation with the Administrator, shall establish and support a basic research and training program…consisting of the following (A) Basic research (including epidemiologic and ecologic studies) which may include each of the following: (i) Advanced techniques for the detection, assessment, and evaluation of the effects on human health of hazardous substances. (ii) Methods to assess the risks to human health presented by hazardous substances. (iii) Methods and technologies to detect hazardous substances in the environment and basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances. (B) Training, which may include each of the following:

		(i) Short courses and continuing education for State and local health and environment agency personnel and other personnel engaged in the handling of hazardous substances, in the management of facilities at which hazardous substances are located, and in the evaluation of the hazards to human health presented by such facilities. (ii) Graduate or advanced training in environmental and occupational health and safety and in the public health and engineering aspects of hazardous waste control. (iii) Graduate training in the geosciences, including hydrogeology, geological engineering, geophysics, geochemistry, and related fields necessary to meet professional personnel needs in the public and private (a) sectors and to effectuate the purposes of this Act.
§311(a)(2)	Research, Development, and Demonstration	The Director of the National Institute for Environmental Health Sciences shall cooperate fully with the relevant Federal agencies referred to in subparagraph (A) of paragraph (5) in carrying out the purposes of this section.
§311(a)(5)	Research, Development, and Demonstration	To assist in the implementation of this subsection and to aid in the coordination of research and demonstration and training activities funded from the Fund under this section, the Secretary shall appoint an advisory council (hereinafter in this subsection referred to as the ''Advisory Council'') which shall consist of representatives of the following: (A) The relevant Federal agencies. (B) The chemical industry. (C) The toxic waste management industry. (D) Institutions of higher education. (E) State and local health and environmental agencies. (F) The general public.
§311(a)(6)	Research, Development, and Demonstration	Within nine months after the date of the enactment of this subsection, the Secretary, acting through the Director of the National Institute for Environmental Health Sciences, shall issue a plan for the implementation of paragraph (1). The plan shall include priorities for actions under paragraph (1) and include research and training relevant to scientific and technological issues resulting from site specific hazardous substance response experience. The Secretary shall, to the maximum extent practicable, take appropriate steps to coordinate program activities under this plan with the activities of other Federal agencies in order to avoid duplication of effort. The plan shall be consistent with the need for the development of new technologies for meeting the goals of response actions in accordance with the provisions of this Act. The Advisory Council shall be provided an opportunity to review and comment on the plan and priorities and assist appropriate coordination among the relevant Federal agencies referred to in subparagraph (A) of paragraph (5).
§311(c)	Research, Development, and Demonstration	HAZARDOUS SUBSTANCE RESEARCH.—The Administrator may conduct and support, through grants, cooperative agreements, and contracts, research with respect to the detection, assessment, and evaluation of the effects on and risks to human health of hazardous substances and detection of hazardous substances in the environment. The Administrator shall coordinate such research with the Secretary of Health and Human Services, acting through the advisory council established under this section, in order to avoid duplication of effort.

§104(i)(4)	Response Authorities	The Administrator of the ATSDR shall provide consultations upon request on health issues relating to exposure to hazardous or toxic substances, on the basis of available information, to the Administrator of EPA
§104(i)(5)(A)	Response Authorities	For each hazardous substance listed pursuant to paragraph (2), the Administrator of ATSDR (in consultation with the Administrator of EPA and other agencies and programs of the Public Health Service) shall assess whether adequate information on the health effects of such substance is available. For any such substance for which adequate information is not available (or under development), the Administrator of ATSDR, in cooperation with the Director of the National Toxicology Program, shall assure the initiation of a program of research designed to determine the health effects (and techniques for development of methods to determine such health effects) of such substance.
§104(i)(6)(C)	Response Authorities	In determining the priority in which to conduct health assessments under this subsection, the Administrator of ATSDR, in consultation with the Administrator of EPA, shall give priority to those facilities at which there is documented evidence of the release of hazardous substances, at which the potential risk to human health appears highest, and for which in the judgment of the Administrator of ATSDR existing health assessment data are inadequate to assess the potential risk to human health as provided in subparagraph (F). In determining the priorities for conducting health assessments
§107(c)	Abatement Action	Within one hundred and eighty days after enactment of this Act, the Administrator of the Environmental Protection Agency shall, after consultation with the Attorney General, establish and publish guidelines for using the imminent hazard, enforcement, and emergency response authorities of this section and other existing statutes administered by the Administrator of the Environmental Protection Agency to effectuate the responsibilities and powers created by this Act.
§120(e)(1)	Federal Facilities	Not later than 6 months after the inclusion of any facility on the National Priorities List, the department, agency, or instrumentality which owns or operates such facility shall, in consultation with the Administrator and appropriate State authorities, commence a remedial investigation and feasibility study for such facility.
§120(e)(6)	Federal Facilities	Administrator, after consultation with other departments, may determine that remedial efforts should be done by another potentially responsible party and may enter into a settlement agreement with such party.

Consultation Provisions in the Resource Conservation and Recovery Act

Section	**Section Title**	**Consultation Requirement**
§2002(a)(1)	Authorities of Administrator	In carrying out this Act, the Administrator is authorized to— (1) prescribe, in consultation with Federal, State, and regional authorities, such regulations as are necessary to carry out his functions under this Act;
§1008(a)	Solid Waste Management Information and Guidelines	Administrator shall consult with Federal agencies, among others, to develop and publish guidelines for solid waste management.

§2001	Office of Solid Waste and Interagency Coordinating Committee	Establishing an Interagency Coordinating Committee for RCRA between EPA, Department of Energy, Department of Commerce, and all other Federal agencies. Includes coordinating research and projects.
§2002(a)(2)-(6)	Authorities of Administrator	(2) consult with or exchange information with other Federal agencies undertaking research, development, demonstration projects, studies, or investigations relating to solid waste; … (5) utilize the information, facilities, personnel and other resources of Federal agencies, including the National Bureau of Standards 1 and the National Bureau of the Census, on a reimbursable basis, to perform research and analyses and conduct studies and investigations related to resource recovery and conservation and to otherwise carry out the Administrator's functions under this Act; and (6) to delegate to the Secretary of Transportation the performance of any inspection or enforcement function under this Act relating to the transportation of hazardous waste where such delegation would avoid unnecessary duplication of activity and would carry out the objectives of this Act and of the Hazardous Materials Transportation Act.
§4002(b)	Federal Guidelines for Plans	Not later than 18 months after enactment, Administrator shall consult with appropriate agencies to promulgate guidelines for the development and implementation of State plans. Such guidelines should be reviewed and revised at least every three years.
§8001(a)	Research, Demonstrations, Training, and Other Activities	The Administrator, alone or after consultation with the [Department of Energy], or [FERC], shall conduct, and encourage, cooperate with, and render financial and other assistance to appropriate public (whether Federal, State, interstate, or local) authorities, agencies, and institutions, private agencies and institutions, and individuals in the conduct of, and promote the coordination of, research, investigations, experiments, training, demonstrations, surveys, public education programs, and studies relating to— (1) any adverse health and welfare effects of the release into the environment of material present in solid waste, and methods to eliminate such effects....
§8001(b)(2)(D)	Research, Demonstrations, Training, and Other Activities	any activities undertaken under provisions of sections 8002 and 8003 as related to energy; as related to energy or synthetic fuels recovery from waste; or as related to energy conservation shall be accomplished through coordination and consultation with the [Department of Energy]